[ECF No. 1]

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

AMGEN, INC., **Plaintiff,** **v.** **CELLTRION USA, INC.,** **Defendant.**	**Civil No. 24-9052 (CPO/EAP)**

OPINION

This matter comes before the Court on Plaintiff Amgen Inc.'s ("Amgen") application pursuant to 28 U.S.C. § 1782 for an order to take discovery for use in a foreign proceeding. *See* ECF No. 1. Amgen filed a brief in support. *See* ECF No. 1-3 ("Amgen Br."). Defendant Celltrion USA, Inc. ("Celltrion USA") opposes Amgen's requested relief. *See* ECF No. 10 ("Celltrion Br."). Amgen has filed a reply brief. *See* ECF No. 21 ("Amgen Reply"). The Court has considered the parties' submissions and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78(b) and Local Civil Rule 78.1. For the following reasons, Amgen's application will be **GRANTED**.

FACTUAL BACKGROUND

A. Amgen's Development and Patent of Denosumab

Amgen is a biotechnology company incorporated in Delaware and headquartered in Thousand Oaks, California. ECF No. 1-8, Declaration of Hyun-Jin Chang ("Chang Decl.") ¶ 4. In 2010, Amgen received Food and Drug Administration ("FDA") approval for Prolia and XGEVA. ECF No. 1-4, Certification of Charles H. Chevalier ("Chevalier Certif.") ¶ 4 & Ex. C

(Prolia product label). Physicians prescribe Prolia to treat patients with a high risk of bone fractures, including patients with osteoporosis. Chang Decl. ¶ 4; Chevalier Certif. ¶ 4 & Ex. C. XGEVA is prescribed to prevent skeletal-related events (e.g., fractures or spinal cord compression) in cancer patients whose cancer has spread to the bone, as well as to treat certain types of tumors. Chang Decl. ¶ 4; Chevalier Certif. ¶ 3 & Ex. C. The active ingredient in both drugs is a monoclonal antibody named denosumab. Chang Decl. ¶¶ 2, 4; Chevalier Cert. ¶ 3 & Ex. B (FDA Imports Entry Data Search). According to Amgen, its scientists have spent decades and millions of dollars creating the denosumab antibody and developing Prolia and XGEVA. Chang Decl. ¶ 4. In addition, Amgen's scientists have made significant advancements in the manufacturing processes for these products to ensure consistency, quality, efficacy, and safety. *Id.*; Amgen Br. at 8.

In relation to its denosumab products, Amgen maintains an extensive portfolio of patents covering both the products and the manufacturing processes. *Id.* ¶ 5. In particular, Amgen holds South Korean Patent No. 10-1038585 (the "'585" Patent), which relates to and claims denosumab—the active ingredient in Prolia and XGEVA—and is the counterpart of Amgen's U.S. Patent No. 7,354,736 (the "Boyle Patent"). *Id.* ¶¶ 5, 7. According to Amgen, the '585 Patent is valid and listed on the Green List of the South Korean Ministry of Food and Drug Safety ("MFDS") in connection with "Prolia Pre-filled Syringe (denosumab)" and "XGEVA Injection (denosumab)." *Id.* The '585 patent expires on March 17, 2025. *Id.* Amgen also has several South Korean patents covering manufacturing processes that can be used to produce denosumab (*i.e.*, the "Korean Manufacturing Patents"), which also have counterpart U.S. Patents. *Id.* ¶ 7. These Korean Manufacturing Patents expire on various dates between 2025 and 2035. *Id.* ¶ 8.

B. Alleged Infringing Activities of Celltrion

Celltrion Inc. is a biotechnology company incorporated and headquartered in South Korea. *Id.* ¶ 6. Celltrion, Inc. is the parent company of Celltrion USA, the current application's target. *Id.*; ECF No. 1 at 1 (Application). Celltrion USA is a Delaware corporation with its principal place of business in Jersey City, New Jersey (collectively, Celltrion, Inc. and Celltrion USA are referred to as "Celltrion"). *Id.*; Amgen Br. at 9; Celltrion Br. at 4.

Celltrion has developed a follow-on drug product (biosimilar) of Prolia/XGEVA using the active ingredient denosumab with the name "CT-P41," which it is now preparing for global launch. Chang Decl. ¶ 6. Celltrion filed a Biologics License Application ("BLA") with the FDA seeking regulatory approval to market its biosimilar CT-P41 in the United States. Compl., *Amgen, Inc. v. Celltrion, Inc.*, Civ. A. No. 24-6497, ECF No. 1 ("Compl.") On May 2, 2024, Celltrion sent a Notice of Commercial Marketing to Amgen in the United States, indicating that Celltrion may begin to commercially market its biosimilar as soon as October 29, 2024. Chang Decl. ¶ 6. Amgen alleges that publicly available records indicate that Celltrion has already imported its biosimilar, CT-P41, into the United States. Chevalier Certif. ¶ 3, Ex. B. Amgen further claims that, through these actions, Celltrion seeks to market its biosimilar before Amgen's U.S. and South Korean Patents expire. Chang Decl. ¶¶ 6, 8; Amgen Br. at 4.

C. Amgen's Pending and Anticipated Litigation Against Celltrion

On May 28, 2024, Amgen and its affiliate, Amgen Manufacturing Limited LLC, filed a patent infringement complaint against Celltrion, Inc. and Celltrion USA in this Court, seeking a declaratory judgment that Celltrion will infringe a number of U.S. patents covering denosumab and the manufacturing methods that may be used to produce denosumab. Chang Decl. ¶ 7; *see* Compl., ECF No. 1, *Amgen, Inc. v. Celltrion, Inc.*, Civ. A. No. 24-6497.

Amgen has also identified the South Korean counterparts of a subset of the U.S. patents that have been asserted in the underlying patent litigation in this Court against Celltrion:

United States Patent	**South Korean Counterpart/Relative**
U.S. 7,364,736 (the "Boyle Patent")	KR10-1038585 (the "'585 Patent")
U.S. 7,928,205 (the "Dillon Patent")	KR10-1370253
U.S. 9,320,816 (the "Zhou Patent")	KR10-1307697
U.S. 10,106,829 (the "Gupta Patent")	KR10-2301034 KR10-2410393 KR10-2519540
U.S. 10,167,492 (the "Leiske Patent")	KR10-2623965
U.S. 10,513,723 (the "Kang Patent")	KR10-2381791
U.S. 10,538,397 (the "Gefroh Patent")	KR10-2370714 KR10-2504829

Chang Decl. ¶ 7.

On July 1, 2024, Amgen filed a patent infringement preliminary injunction action before the Seoul Central District Court (the "South Korean Court"), under the caption *Amgen Fremont, Inc. et al. v. Celltrion, Inc.*, Case. No. 2024 Kahap 20960 ("South Korean Proceedings"). Chang Decl. ¶¶ 2, 9. In the South Korean Proceedings, Amgen Inc. and Amgen Fremont, Inc. seek a preliminary injunction to prohibit Celltrion from manufacturing and stockpiling denosumab biosimilar drug substance and drug products—which allegedly infringe the '585 Patent—in South Korea. *Id.*

Because South Korean law requires that preliminary injunction proceedings be brought separately from a main patent infringement action seeking permanent relief, Amgen anticipates filing a main action in South Korea, seeking a permanent injunction and damages based upon Celltrion's infringement of the '585 Patent. *Id.* ¶¶ 2, 10-11; ECF No. 1-9, Declaration of Sung Jai Choi ("Choi Decl.") ¶ 7. Amgen further contemplates additional preliminary injunction and main

action proceedings in South Korea to prevent the ongoing and/or planned infringement of Amgen's South Korean Manufacturing Patents. Chang Decl. ¶ 2.

To prevail in a South Korean preliminary injunction action, the patentee has the burden to show likelihood of success on the merits of the infringement claim and that irreparable harm will imminently result if the preliminary injunction is not granted. Choi Decl. ¶ 8. While a preliminary injunction action may be filed with only *prima facie* evidence of infringement, South Korea limits litigation discovery, thereby requiring a patentee to obtain and present the evidence it needs to prove infringement and harm through its own devices, without expecting discovery from the alleged infringer. *Id.* ¶ 9. Nonetheless, Korean courts are receptive to receiving and considering evidence, including that obtained by an action under 28 U.S.C. § 1782. *Id.* If evidence of infringement is not presented in the course of preliminary injunction proceedings, the preliminary injunction action may be dismissed. *Id.*

Unlike in the United States, South Korean legal proceedings do not provide for pretrial discovery or other mechanisms to request discovery from the other party. *Id.* ¶ 10. Instead, under Article 345 of the South Korean Code of Civil Procedure, a party must petition the court to order the other party to produce requested discovery, and it will be ordered only if the petitioning party can establish with specificity that the requested documents exist and contain probative evidence. *Id.* According to Amgen, discovery in a preliminary injunction action is far more limited than in a main patent infringement action, due to the urgency of the requested relief. *Id.* Indeed, the South Korean Court rarely allows discovery to establish the merits of a preliminary injunction. *Id.*

D. Amgen's Current Application Pursuant to 28 U.S.C. § 1782

In furtherance of its current and anticipated proceedings in South Korea, Amgen filed the present application pursuant to 28 U.S.C. § 1782 to obtain documents and testimony from Celltrion

USA for use in the South Korean Proceedings. Amgen's proposed subpoena provides the following relevant definitions:

> "Celltrion USA," "You," and "Your" shall mean Celltrion USA, Inc. and shall include Your predecessors, successors, subsidiaries, divisions, departments, assigns, parent corporations, foreign and domestic affiliates, organizational operating units, and each other person or business entity, directly or indirectly, wholly or in part, owned or controlled by it; and all present or former partners, principals, employees, officers, directors, agents, legal representatives, consultants or other persons acting for or on its behalf, and each of its respective predecessors, successors, subsidiaries, divisions, departments, assigns, parent corporations, foreign and domestic affiliates, organizational operating units, and each other person or business entity, directly or indirectly, wholly or in part, owned or controlled by the entity.

Chevalier Certif., Ex. A (Proposed Subpoena ("Subpoena")) ¶ 1.

> "Celltrion, Inc." shall mean Celltrion, Inc. and its predecessors, successors, subsidiaries, divisions, departments, assigns, parent corporations, foreign and domestic affiliates, organizational operating units, and each other person or business entity, directly or indirectly, wholly or in part, owned or controlled by them; and all present or former partners, principals, employees, officers, directors, agents, legal representatives, consultants or other persons acting for or on its behalf, and each of their respective predecessors, successors, subsidiaries, divisions, departments, assigns, parent corporations, foreign and domestic affiliates, organizational operating units, and each other person or business entity, directly or indirectly, wholly or in part, owned or controlled by the respective entity.

Id. ¶ 2.

> "Celltrion" shall mean Celltrion, Inc. and/or Celltrion USA, separately or collectively.

Id. ¶ 3.

The Subpoena requests eighty-two different categories of documents and testimony. *See* Subpoena, Requests for Production ¶¶ 1-82. The documents requests and testimony topics are directed towards the identity and characterization, manufacturing, import/export, and current

approval status of Celltrion's products containing denosumab, including the CT-P41 biosimilar, along with any agreements relating to CT-P41. *Id.*; Chang Decl. ¶ 12. Specifically, Amgen seeks:

> [I]nformation regarding the amino acid sequence of Celltrion's proposed biosimilar denosumab active ingredient; the dates, locations, amounts, and purposes of manufacture of Celltrion's denosumab and/or CT-P41 products; details regarding the manufacturing processes used by Celltrion to manufacture denosumab and CT-P41; information regarding the dates, destinations, amounts, future exports and purposes of exports of Celltrion's denosumab and/or CT-P41 products to the U.S. or any other countries; information regarding the product approval application status for Celltrion's CT-P41 product in the U.S. or any other countries, including dates of application filings, whether the approval relates to Prolia or XGEVA, indications for which approval is sought, and future product approval plans; and any agreements relating to the manufacture, import, export, storage, and/or sales of denosumab and/or CT-P41.

Chang Decl. ¶ 12.

Celltrion USA contends that the application should be denied, or at least modified, because it exceeds the limitations of both § 1782 and the Federal Rules of Civil Procedure to require Celltrion USA to provide discovery from Celltrion, Inc.—a separate Korean corporate entity that neither resides in nor is found in this District. *See* Celltrion Br. at 1. Celltrion emphasizes that Celltrion, Inc. and Celltrion USA are separate entities and that Celltrion USA will be responsible for the marketing, sale, and distribution of Celltrion, Inc.'s proposed denosumab biosimilar, CT-P41, in the United States. Celltrion Br. at 1; ECF No. 10-1, Declaration of Bonjoong Kim ("Kim Decl.") ¶ 6. According to Celltrion, Celltrion USA does not have a regulatory department; did not file a BLA relating to CT-P41 or any other denosumab product; is not involved in communication with the FDA about any such BLA; and is not the U.S. agent for any denosumab BLA filing. *Id.* ¶¶ 6-8.

DISCUSSION

Section 1782 of Title 28 of the United States Code provides in pertinent part:

> The district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal, ... The order may be made . . . upon the application of any interested person and may direct that the testimony or statement be given, or the document or other thing be produced, before a person appointed by the court.

28 U.S.C. § 1782(a). Section 1782 "'was designed to facilitate the conduct of litigation in foreign tribunals, improve international cooperation in litigation, and put the United States into the leadership position among world nations in this respect.'" *In re Biomet Orthopaedics Switzerland GmBh*, 742 F. App'x 690, 695 (3d Cir. 2018) (quoting *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191-922 (3d Cir. 1999)).

To decide an application under § 1782, a court "must first determine whether certain statutory requirements are met." *In re O'Keeffe*, 646 F. App'x 263, 265 (3d Cir. 2016) (footnote omitted). The basic statutory requirements are: "(1) the person from whom discovery is sought resides in the district; (2) the request seeks the 'testimony or statement' of a person or the production of a 'document or other thing'; (3) the discovery is for use in proceedings before a foreign or international tribunal; and (4) the application is made by either a 'foreign or international tribunal' or by an 'interested party.'" *Id.* at 265 n.4 (quoting 28 U.S.C. § 1782).

Once these statutory requirements are satisfied, the reviewing court may then consider other factors in determining whether to exercise its discretion to grant the application. *Id.* at 265-66. The United States Supreme Court in *Intel Corporation v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 264-65 (2004), identified four factors relevant to this discretionary determination ("*Intel* factors"). First, the court can consider whether "the person from whom discovery is sought is a

participant in the foreign proceeding," since "nonparticipants in the foreign proceeding may be outside the foreign tribunal's jurisdictional reach," necessitating § 1782(a)'s aid. *Id.* at 264. Second, a court "may take into account the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance." *Id.* (citation omitted). Third, a district court may consider whether the application "conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States." *Id.* at 265. Finally, the court should consider whether the request is "unduly intrusive or burdensome" that "may be rejected or trimmed." *Id.*

Amgen contends that its application satisfies all statutory requirements of § 1782 and asserts that the Court should exercise its discretion to compel the discovery under the *Intel* factors. Celltrion USA counters that the application fails to meet the first statutory factor; that is, the person from whom discovery is sought is a participant in the foreign action. Celltrion Br. at 8. It also argues that the first and fourth *Intel* factors, as well as the requirements of the existing confidentiality order in the underlying patent litigation in this Court, warrant the discretionary denial of Amgen's application. *Id.* Alternatively, Celltrion posits that if the Court finds that Amgen's application should be granted, the Court should modify the requests "to address the overreach of the subpoena." *Id.* The Court considers these arguments individually.

A. Statutory Factors Under 28 U.S.C. § 1782

The only disputed statutory requirement between the parties concerns the first factor—that the person from whom discovery is sought resides in this District. Because the parties agree that the other factors have been satisfied, the Court only addresses the first requirement.[1]

[1] Amgen's application establishes—and Celltrion does not dispute—that the request seeks the production of a document or thing for use in the South Korean Proceedings and that the

Amgen posits that the first statutory requirement is satisfied because Celltrion USA—the target of the application—has its principal place of business in New Jersey. Amgen Br. at 18-19. Celltrion disagrees, arguing that Amgen's § 1782 application seeks to "circumvent corporate formalities" to access documents controlled and maintained by Celltrion USA's corporate Korean-based patent, Celltrion, Inc. Celltrion Br. at 9. Celltrion further contends that Amgen's proposed Subpoena defines Celltrion USA by reference to its parent and corporate affiliates and seeks documents from "Celltrion" collectively, including both Celltrion USA and Celltrion, Inc. *Id.* Finally, Celltrion argues that the Subpoena seeks documents that are located in Korea, in Celltrion Inc's possession, for use in Korea. *Id.* at 10.

Celltrion USA's argument is misplaced. Section 1782 requires only that the person from whom the documents are sought resides in or can be found in the District; it does not require that the documents be maintained or found in this District. 28 U.S.C. § 1782(a). Once the target of the application is deemed to reside within a particular district, § 1782 "'incorporates by reference the scope of discovery permitted by the Federal Rules of Civil Procedure.'" *In re Yilport Holding A.S.*, No. 22-3028, 2023 WL 2140111, at *3 (D.N.J. Feb. 21, 2023) (quoting *Bayer AG*, 173 F.3d at 192). Federal Rule of Civil Procedure 45(a)(1)(A)(iii) applies to the substance of the subpoena and permits a party to serve a request to "produce designated documents, electronically stored information, or tangible things in that person's possession, custody, or control . . . ." Fed. R. Civ. P. 45(a)(1)(A)(iii); *see In re Ex Parte Global Energy Horizons Corp.*, 647 F. App'x 83, 86 (3d Cir. 2016) (noting that § 1782 "expressly incorporates the Federal Rules of Civil Procedure" and that Rule 45 circumscribes discovery under § 1782). In the context of Rule 45, "control has been found where a party has the 'legal right to obtain the documents required on demand.'" *In re Novo*

application is being made by Amgen, which is an interested party in the South Korean Proceedings. 28 U.S.C. § 1782.

Norodisk Secs. Litig., 530 F. Supp. 3d 495, 502 (D.N.J. 2021) (citations omitted). "[S]o long as the party has the legal right or ability to obtain the documents from another source upon demand, that party is deemed to have control. *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142, 160 (3d Cir. 2004). Indeed, because "'[t]he Federal Rules of Civil Procedure . . . authorize extraterritorial discovery so long as the documents to be produced are within the subpoenaed party's possession, custody, or control . . . Section 1782 likewise allows extraterritorial discovery.'" *In re Rosa Carolina Germano Dos Santos*, No. 22-1567, 2023 WL 4993673 (D.N.J. Aug. 4, 2023) (quoting *In re Del Valle Ruiz*, 939 F.3d 520, 523 (2d Cir. 2019)).

In the context of a document demand directed to a corporate subsidiary for records in the possession of the parent company, "control has been found to exist where the 'alter ego' doctrine warranted piercing the corporate veil." *Gerling Int'l Ins. Co. v. C.I.R.*, 839 F.2d 131, 140 (3d Cir. 1988). "[A]pplication of the alter ego doctrine is rare, given that 'the separate and distinct corporate identities of a parent and subsidiary are not readily disregarded.'" *TQ Delta, LLC v. Samsung Elecs. Am., Inc.*, No. 21-16580, 2021 WL 6049908, at *3 (D.N.J. Dec. 20, 2021) (quoting *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 233 F.R.D. 143, 145 (D. Del. 2005)).

Control may also exist where the subsidiary is an agent of the parent in the transaction giving rise to the litigation. *Gerling*, 839 F.2d at 140. In such cases, "[w]here the relationship is thus such that the agent-subsidiary can secure documents of the principal-parent to meet its own business needs and documents helpful for use in the litigation, the courts will not permit the agent-subsidiary to deny control for purposes of discovery by an opposing party." *Id.* at 141 (citation omitted). Notably, however, "district courts within the Third Circuit 'have declined to apply a broader definition of "control" that would also include an inquiry into the practical ability of the

subpoenaed party to obtain documents.'" *TQ Delta*, 2021 WL 6049908, at *3 (quoting *In re Novartis & Par Antitrust Litig.*, No. 19-149, 2019 WL 5722055, at *7 (E.D. Pa. Nov. 5, 2019)). "The burden is on the party seeking discovery to establish the requisite control by the subpoenaed party over the documents sought." *Id.* (citing *Novo Norodisk*, 530 F. Supp. 3d at 502).

The enforceability of an application under 28 U.S.C. § 1782 does not hinge on questions about custody and control of the documents. *See In re Cal. State Tchrs' Ret. Sys.*, No. 16-4251, 2016 WL 7477753, at *2 (D.N.J. Dec. 28, 2016)*, aff'd, In re Cal. State Tchrs' Ret. Sys.*, No. 16-4251, 2017 WL 1246349 (D.N.J. Apr. 3, 2017). Rather, § 1782 only requires that the person from whom the documents are sought resides in or can be found in the district. 28 U.S.C. § 1782. To that end, "regardless of references to parents, subsidiaries, or affiliates, only those documents in the possession [of the subpoenaed party] are subject to the subpoena." *In re Cal. State Tchrs.' Ret. Sys.*, 2016 WL 7477753, at *2. The fact that some of a foreign parent-corporation's documents may be in the possession of the subpoenaed United States subsidiary—and thus may need to be produced under the subpoena—does not "amount to an improper application of Section 1782." *Id.*

Applying these principles here, the Court finds that the first statutory factor is satisfied. The application is directed to Celltrion USA, which for purposes of § 1782, resides in New Jersey. While the proposed Subpoena broadly defines Celltrion USA as including all "subsidiaries," "parent corporations," and "foreign and domestic affiliates," and seeks documents from "Celltrion," which is defined to include both Celltrion USA and Celltrion, Inc., ECF No. 1-5 (Section 1782 application) at Schedule A ¶¶ 1, 3, the Subpoena itself is only directed to and enforceable against Celltrion USA. *See In re Rosa Carolina Germano Dos Santos*, 2023 WL 4993673, at *3-4 (finding that even though subpoenas sought information about entities outside the district, including the respondents' foreign parent corporation, the subpoena only sought

materials within the subpoenaed party's custody, possession, and control). Thus, Amgen may only obtain from Celltrion USA documents that are within its possession, custody, and control. Issues of whether certain documents fall within that reach are better reserved for specific objections to the subpoena, and Amgen will bear the burden on such questions. *See TQ Delta*, 2021 WL 6049908, at *3. For purposes of determining the propriety of this application, it suffices to find that Celltrion USA resides in this District.

B. The Discretionary *Intel* Factors

Having found that Amgen has satisfied all the statutory factors, Celltrion USA, as the party opposing the application, bears the burden of establishing that the discretionary *Intel* factors weigh against granting the application. *See Bayer AG*, 173 F.3d at 190. The Supreme Court devised the *Intel* factors to aid a district court in determining whether to exercise its discretion in permitting the use of § 1782. *In re Poblete*, No. 23-20477, 2024 WL 3738854, at *3-4 (Aug. 9. 2024). "'The *Intel* factors are not to be applied mechanically.'" *In re Alpine (BVI) L.P.*, No. 24-337, 2024 WL 4336824, at *3 (D.N.J. Sept. 27, 2024) (quoting *Kiobel v. Cravath Swaine & Moore, LLP*, 895 F.3d 238, 245 (2d Cir. 2018)). Moreover, no single factor is dispositive or should be accorded more weight than others. *Id.* (cleaned up). Ultimately, the decision whether to grant a § 1782 application falls within "the Court's broad discretion." *Id.* (citations omitted).

Although Celltrion USA disputes only the first and fourth factors, for purposes of comprehensiveness, the Court addresses all four factors.

1. Whether the Evidence Sought Is Within the Foreign Tribunal's Reach

"The first *Intel* factor asks whether the discovery sought is 'unobtainable' in the foreign forum because it is outside of the foreign tribunal's jurisdictional reach." *SPS Corp. I v. Fundo De Investimento Em Direitos Creditórios Não Padronizados,* 110 F.4th 586, 592 (3d Cir. 2024)

(citing *Intel*, 542 U.S. at 264). Under this factor, the focus rests on the foreign court's "jurisdictional reach" and "not simply whether the party from whom discovery is sought is a participant to the foreign proceedings." *Id.*

Amgen contends that Celltrion USA—the named respondent of the present § 1782 application—is neither a party to the pending South Korean Proceedings nor subject to jurisdiction in South Korea. Chang Decl. ¶ 17. Thus, Amgen argues that the requested discovery remains outside the foreign tribunal's jurisdictional reach, leaving evidence from Celltrion USA unobtainable absent § 1782 aid. *Id.*

Celltrion USA responds that "[t]his factor turns primarily on whether the Court limits discovery to only Celltrion USA." Celltrion Br. at 12. If the discovery is so limited, Celltrion USA concedes that it is not a participant in the foreign proceeding and this factor weighs in favor of granting the application. *Id.* Celltrion USA argues, however, that "if this Court were to take Amgen up on its invitation to treat Celltrion USA and Celltrion Korea as one and the same entity over Celltrion USA's objection, then the 'combined entity' would be a participant in the foreign proceeding because Celltrion Korea is the defendant in the present preliminary injunction proceedings." *Id.*

Celltrion's argument is a red herring. As discussed above, Celltrion USA is the only target of the present § 1782 application, and only evidence within Celltrion USA's possession, custody, and control remains subject to discovery under the subpoena. Celltrion USA concedes that it is not a party to the South Korean Proceedings, and thus, such evidence falls outside of the reach of the Korean courts. Accordingly, this factor favors granting the application.

2. Nature of Foreign Tribunal, Character of the Proceedings Abroad, and Receptivity of the Foreign Government to U.S. Federal-Court Judicial Assistance

The second *Intel* factor examines "the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal court judicial assistance." *In re O'Keeffe*, 646 F. App'x at 266. "[W]here a foreign tribunal opposes such aid, granting discovery would undermine the spirit of comity underlying § 1782 by discouraging foreign tribunals from 'heeding similar sovereignty concerns posited by our governmental authorities to foreign courts.'" *In re Application for Discovery for Use in Foreign Proc.*, No. 17-4269, 2019 WL 168828, at *8 (D.N.J. Jan. 10, 2019) (quotation omitted). The proper inquiry is not "whether *particular* evidence would be admissible in a foreign court" but rather, the focus is on the general "receptivity to 'U.S. federal-court judicial assistance.'" *In re O'Keeffe*, 646 F. App'x at 267 (emphasis in original) (quoting *Intel*, 542 U.S. at 264). The party opposing discovery bears the burden of proof regarding receptiveness and must produce "'authoritative proof that a foreign tribunal would reject evidence obtained with the aid of § 1782." *In re RH2 Participaes Societrias LTDA*, No. 23-2025, 2024 WL 3598379, at *5 (D.N.J. July 31, 2024) (quotation and citation omitted).

Here, Amgen has produced a declaration from Sung Jai Choi, a Korean law expert. *See* Choi Decl. ¶¶ 1, 4(a). According to Choi, the South Korean Court would not raise any issues regarding the admissibility of the evidence Amgen seeks in this application. *Id.* ¶ 10. He opines that "Article 202 of the South Korean Civil Procedure Act gives South Korean courts substantial discretion to consider any probative evidence that may be presented, including evidence obtained through foreign proceedings such as a Section 1782 application." *Id.* ¶ 16. Ultimately, Choi concludes that "South Korean courts are generally receptive to Section 1782 discovery and

liberally admit evidence obtained by parties[.]" *Id.* ¶ 19. As Celltrion USA has produced no evidence to the contrary, the Court finds that this factor weighs in favor of granting the application.

3. Whether the Applicant Is Trying to Circumvent Foreign Proof Gathering Restrictions

The third *Intel* factor asks, "whether the subpoena request conceals an attempt to circumvent foreign proof-gathering restrictions." *In re O'Keeffe*, 646 F. App'x at 268. "[T]he law is clear that an applicant is not required to seek discovery in the foreign forum before filing a § 1782 application." *In re RH2 Participaes Societrias*, 2024 WL 3598379, at *6 (citing *In re O'Keeffe*, 646 F. App'x at 268; *Cal. State Tchrs.' Ret. Sys.*, 2020 WL 6336199, at *9). Moreover, "that the discovery may be unobtainable in the foreign forum is not a basis to deny an application under § 1782." *Id.* (citing *In re Chevron*, 633 F.3d 153, 163 (3d Cir. 2011). Indeed, the fact that a foreign jurisdiction "does not offer a mechanism for general pretrial discovery comparable to that obtainable in the United States" creates "a textbook predicate for a successful § 1782 petition, given courts' consistently liberal interpretation of the statute and its objective 'to assist foreign tribunals in obtaining relevant information that the tribunals may find useful but, for reasons having no bearing on international comity, they cannot obtain under their own laws.'" *Kulzer v. Esschem, Inc.*, 390 F. App'x 88, 92 (3d Cir. 2010) (quoting *Intel*, 542 U.S. at 262).

Here, Amgen presents evidence that in South Korea, a patentee cannot expect to receive discovery regarding infringement during a preliminary injunction action. Choi Decl. ¶ 9. Unlike in the United States, "there is no pretrial discovery in South Korea, and indeed South Korean legal proceedings do not provide parties mechanisms to directly request any discovery from the other party." *Id.* ¶ 10. Amgen's expert, Choi, further opines that it is "extremely unlikely that the South Korean Court will permit Amgen to request any discovery from Celltrion in the South Korean Proceedings that would be necessary for Amgen to establish infringement of any of its patents,

particularly in view of the specificity that would be required for Amgen's requests." *Id.* In its opposition, Celltrion USA does not dispute this evidence.

The Court finds that the § 1782 application does not constitute an attempt to circumvent foreign discovery rules. Rather, it is precisely the type of foreign assistance that a foreign tribunal may welcome to obtain useful relevant information unobtainable under its own laws. Therefore, the Court finds that this factor favors granting the application.

4. Undue Burden

The final *Intel* factor requires courts to consider whether the discovery sought is "unduly intrusive or burdensome." *Intel*, 542 U.S. at 265. "'Assessment of the fourth factor is virtually identical to the familiar "overly burdensome" analysis that is integral to the Federal Rules.'" *Cal. State Tchrs.' Ret. Sys.*, 2020 WL 6336199, at *10 (quoting *In re Ex Parte Global Energy Horizons Corp.*, 647 F. App'x at 86). "Thus, the requested discovery must be reasonably calculated to lead to the discovery of admissible evidence, consistent with rule 26(b)(1), and avoid imposing undue burden or expense on the subpoenaed entity, pursuant to Rule 45(d)." *In re Poblete*, No. 23-20477, 2024 WL 3738554, at *9 (D.N.J. Aug. 9, 2024) (citation omitted).

Here, Amgen contends that it "seeks narrowly tailored discovery from Celltrion USA regarding the nature of the biosimilar product, CT-P41, and the manufacturing processes, importing activities, supply chain, and launch information for the importation, marketing, and commercialization of Celltrion's denosumab biosimilar in the U.S., as well as other countries." Amgen Br. at 26. Amgen also seeks discovery on the status of Celltrion, Inc.'s regulatory applications in several countries and regions around the world. *Id.* Amgen asserts that it "has reason to believe that Celltrion USA has possession, custody, and/or control of the documents and information sought by this Application" because "Celltrion USA is the filer of the BLA in the

United States"; and thus, it may "have information regarding the location, timing, and processes used to manufacture and produce its biosimilar." *Id.* at 27. Finally, Amgen posits that to the extent that the requested material is not in Celltrion USA's physical possession, it may have "a right of access to such materials," bringing it within its possession, custody, or control,. *Id.*

Celltrion USA responds that Amgen's subpoena "would require Celltrion USA to search every other Celltrion entity's files despite a lack of possession, custody, or control of those entities' documents." Celltrion Br. at 13. Moreover, Celltrion claims that it would have to search for "documents relating to every denosumab product for which any Celltrion entity seeks approval anywhere in the world." *Id.* As for the subset of categories for which Celltrion USA might have some responsive documents, Celltrion asserts that Amgen has provided no explanation for how those documents would be relevant to the South Korean Proceedings related to Korean Process Patents. *Id.* at 13-14.

The Court finds that Celltrion USA's claims of undue burden are unfounded. Generalized objections as to relevancy do not bear on the broader questions of whether the requests are "proportional to the needs of the case" and "designed to avoid imposing undue burden or expense." *In re Yilport Holding A.S.*, 2023 WL 2140111, at *8 (quotation omitted). To the extent the subpoena may encompass materials ultimately not relevant to the claims or defenses in the South Korean Proceedings, such overbreadth is not a reason to deny a § 1782 application outright. *See In re RH2 Participaes Societras LTDA*, 2024 WL 3598379, at *8 (declining to deny a § 1782 application because of overbreadth and directing the parties to meet and confer to appropriately narrow the subpoena). Indeed, Celltrion USA has specifically preserved its right to raise objections if the Court grants the application. Celltrion Br. at 14 n.4.

Moreover, to the extent Celltrion USA argues that the subpoena seeks documents that "Celltrion USA is unlikely to have," *id.* at 13, it fails to establish undue burden. As previously discussed, Federal Rule of Civil Procedure. 45—which governs the substance of a subpoena issued pursuant to a non-party under Section 1782—requires only that the target person/entity produce information within its "possession, custody, or control." Fed. R. Civ. P. 45(a)(1)(A)(iii). To that end, Celltrion USA will only need to produce documents that are in its physical possession or for which it has the "legal right to obtain the documents required on demand." *Novo Nordisk*, 530 F. Supp.3d at 502 (citations omitted). Should Celltrion USA not have the legal right to obtain the requested documents—regardless of its practical ability to do so—it may raise this issue during a meet and confer with Amgen and if necessary, object on that basis.[2]

Finally, Celltrion USA contends that the absence of a confidentiality order governing the production of the requested material regarding its future launch plans warrants a denial of the application. Celltrion Br. at 14. Although Amgen originally proposed modeling a confidentiality order after the Stipulated Confidentiality Order in *Amgen v. Celltrion*, Civ. A. No. 24-6497 or modifying that Stipulated Confidentiality Order to permit all documents produced to be used in Korea, Celltrion USA claims that Amgen has yet to propose a confidentiality order. Celltrion USA now argues that requiring production of documents without a confidentiality order in place would render the subpoena unduly intrusive. Celltrion Br. at 3.

Celltrion USA's concerns are easily assuaged, however, by an order from this Court directing the parties to meet and confer and enter into a confidentiality agreement that will govern

[2] Amgen's reply brief contends that Celltrion USA implicitly acknowledges that it has control over the discovery sought. Amgen Reply at 11. The Court need not address this argument. Speculative questions as to whether Celltrion USA has possession, custody, or control over certain documents potentially responsive to the subpoena does not factor into whether the § 1782 application should be granted.

the documents produced under the subpoena. *See In re Posco*, 794 F.3d 1372, 1376-77 (Fed. Cir. 2015) (noting that the *Intel* factors can support the modification of an existing protective order to allow foreign cross-use). Whether the parties choose to modify the existing confidentiality order from Civil Action 24-6497 to remove the foreign use prohibition[3] or to draft an entirely new confidentiality order is irrelevant to the propriety of the application. Moreover, as Amgen notes, the Korean legal system has existing confidentiality procedures in place, and the Korean courts routinely deny third parties access to materials submitted to the court unless they demonstrate a concrete interest in the lawsuit. *See* ECF No. 22-3, Second Declaration of Hyun-Jin Chang ¶¶ 1-3. Celltrion USA provides no legal basis on which the Court should deny the present § 1782 application simply because the parties have yet to enter into a confidentiality order.

CONCLUSION

Having considered Section 1782's statutory requirements and the discretionary *Intel* factors, the Court grants Amgen's application. In so doing, the Court orders the parties to meet and confer on a confidentiality agreement to address the production of responsive documents pursuant to the subpoena and the limits of their use. Finally, the Court notes that Celltrion has not waived any right to object to particular discovery requests.

An appropriate Order follows.

s/Elizabeth A. Pascal
ELIZABETH A. PASCAL
United States Magistrate Judge

cc: Hon. Christine P. O'Hearn, U.S.D.J.

[3] The Stipulated Confidentiality Order in Civil Action No. 24-6497 states that information "shall not be used by the Receiving Party in any foreign or domestic litigation . . . ." Civ. A. No. 24-6497, ECF No. 69 (Stipulated Confidentiality Order) ¶ 29. Celltrion USA objects to any request to modify that Confidentiality Order because Amgen agreed to it weeks after filing the South Korean Proceedings. The Court encourages Celltrion USA to reconsider its position.